

**REMARKS**

Claims 1, 14 and 23 are pending. Reconsideration and allowance of the pending claims in view of the remarks below is respectfully requested.

**The Subject Matter of the Pending Claims is Novel**

Claims 1, 14 and 23 were rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by WO2002/70539, which was filed on March 5, 2002 and claims the benefit of priority of U.S. Application No. 09/799,451, which was filed on March 5, 2001, and is now U.S. Patent No. 6,783,969.

Applicants submit with this response a declaration by the inventors of the present invention made under 37 C.F.R. § 1.131, to "swear behind" the cited reference. Applicants submit a signed declaration together with an email sent on January 3, 2001, more than two months before the filing date of U.S. Application No. 09/799,451, which clearly shows that the subject matter encompassed by the claims was in the inventors' possession. Two inventors, Drs. Faris and Mitchell did not respond to our repeated requests for their signatures on the Rule 131 declaration. As such, we enclose with this response two declarations under 37 C.F.R. § 1.183 to suspend the rules and permit the Office to accept our Rule 131 declaration without the signature of all the inventors.

As discussed more fully in the declaration, the email sent by Dr. Mitchell contains a nucleotide sequence and an amino acid sequence. The nucleotide sequence disclosed in the email contains each and every nucleotide disclosed in SEQ ID NO:1 of the present invention. The amino acid sequence disclosed in the email contains each and every amino acid residue disclosed in SEQ ID NO:2 of the present invention. As such, this evidence is sufficient to demonstrate that the subject matter encompassed by the pending claims was in possession of the inventors prior to the earliest filing date of the cited reference. Accordingly, the declaration submitted with this response is sufficient to overcome the present rejection.

Notwithstanding the dispositive nature of the evidence provided in the declaration, certain comments made in the Office Action mailed January 3<sup>rd</sup>, 2006 necessitate a brief review of the law regarding what constitutes an adequate Rule 131 declaration.

Antedating a Reference with a Rule 131 Declaration

An applicant for a patent may antedate a reference by submitting a declaration containing sufficient facts and evidence which establish invention of the subject matter of the rejected claim prior to the effective date of the reference. 37 C.F.R. § 1.131(a). An appropriate declaration under 37 C.F.R. § 1.131, however, need not show more than that which the reference shows. *In re Stryker*, 435 F.2d 1340, 1341 (CCPA 1971); M.P.E.P. § 715.02. The showing of facts required of an adequate Rule 131 declaration need to be of sufficient weight and character as to establish either a reduction to practice prior to the effective date of the reference or conception of the invention prior to the effective date of the reference and diligence. 37 C.F.R. § 1.131(b). Thus, diligence need not be alleged in each and every Rule 131 declaration. On those occasions where it is required, diligence must be shown for a period beginning just prior to the effective date of the reference and ending with the date of a reduction to practice. M.P.E.P. § 715.07(a).

Some inventions, such as those relating to genetic material, present special considerations regarding the issues of conception and reduction to practice. “Conception is the ‘formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice.’” *Amgen v. Chugai Pharmaceuticals, Co.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991)(citations omitted). “In some instances, an inventor is unable to establish conception until he has reduced the invention to practice through a successful experiment. This situation results in a simultaneous conception and reduction to practice.” *Id.* Regarding genes, the Federal Circuit has held that “when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, *i.e.*, until after the gene has been isolated.” *Id.*

In the present case, the Office alleged that the evidence provided submitted in the previous Rule 131 declaration was insufficient because it did not establish diligence from a date prior to the effective date of the cited reference (March 5, 2001) to either a constructive reduction to practice or an actual reduction to practice. Office Action, page 4. The Office goes on to allege that the evidence provided was insufficient to show that Applicants were in possession of the claimed subject matter prior to effective date of the cited reference. *Id.* These allegations are in error as a matter of fact and law.

As discussed above and in the Rule 131 declaration, Applicants were in possession of the claimed amino acid and nucleotide sequences prior to the effective date of the cited reference. Applicants' position is supported by the email of Dr. Mitchell, which clearly displays the date of January 3, 2001. The mailing date of the email is more than two (2) months prior to the effective date of the cited reference. As is also demonstrated in the exhibits to the declaration, the amino acid and nucleotide sequences disclosed in the email contain each and every amino acid and nucleotide recited in the pending claims. This is shown clearly and unambiguously in Exhibits B and C of the declaration which compare the nucleotide and amino acid sequences of the email to SEQ ID NOS: 1 and 2, where the sequences of the application are disclosed clearly and unambiguously in Dr. Mitchell's email. Taken as a whole, the proffered evidence is more than sufficient to support Applicants' contention that they were in possession of the claimed subject matter prior to the effective date of the cited reference.

The last point raised by the Office to be addressed here is that of diligence. The Office alleged that the submitted evidence was insufficient to establish diligence for the relevant period. Office Action, page 4. Applicants submit that diligence need not be shown here because no time transpired from the moment of conception and reduction to practice. As discussed above, because of the unique nature of genetic material, in which conception and reduction to practice occur simultaneously. Thus, Applicants' declaration antedating the cited reference need not allege diligence.

In view of the declaration of the inventors, the evidence provided therewith, and the remarks provided above, Applicants submit that they have sufficiently demonstrated their prior invention of the subject matter recited in the claims. As such, the present rejection should be withdrawn.

Double Patenting

The Office has provisionally rejected claims 1, 14 and 23 under the judicially created doctrine of obvious-type double patenting as allegedly being unpatentable over claims 1, 12-17, 19, 21, 26, 51 and 52 of copending Application No. 10/099,460. Applicants submitted a terminal disclaimer over this application on April 18, 2005. The Office has indicated in the latest action that a showing that the two applications were commonly owned will obviate this rejection. To this end, Applicants refer the Office to the recorded assignments of both cases, which can be found at Reel/Frame Nos. 012,044/0106 and 013,455/0044, corresponding to the present case and Application No. 10/099,460, respectively. This showing is sufficient to obviate the present rejection. As such, Applicants request that the present rejection be withdrawn in view of the recorded assignments.

Interview

Applicants thank the Examiner for the courtesy shown during the telephonic interview conduct with Applicants' representative. No agreement was reached during the interview. Nevertheless, the Examiner's comments were helpful and are incorporated into the present response.

**CONCLUSION**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 511582003500. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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